

# Notice of Allowability

## Application No.

09/964,899

## Examiner

Valarie Bertoglio

## Applicant(s)

COHEN ET AL.

## Art Unit

1632

### -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/28/2004.
2. ☒ The allowed claim(s) is/are 3,30 and 112-114.
3. ☐ The drawings filed on N/A are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

- |   |  |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892)  | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)                              |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br>Paper No./Mail Date <u>1101</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br>Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment                                      |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br>of Biological Material          | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance                     |
|   | 9. <input type="checkbox"/> Other _____  |

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### EXAMINER'S AMENDMENT

The After Final Amendment filed 10/28/2004 has been received and entered.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Regina Bautista on 11/08/2004 and 11/10/2004.

An extension of time under 37 CFR 1.136(a) is required in order to make an examiner's amendment which places this application in condition for allowance. During a telephone conversation conducted on 11/08/2004, Regina Bautista requested an extension of time for 1 MONTH(S) and authorized the Director to charge Deposit Account No. 19-0134 the required fee of \$110 for this extension and authorized the following examiner's amendment. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

The application has been amended as follows:

In the claims:

3 (renumbered as 1). (Currently Amended) A transgenic fly whose genome comprises a DNA sequence encoding a polypeptide comprising [the] an Abeta portion of human amyloid precursor protein (APP) APP wherein said DNA sequence encodes Abeta42 (SEQ ID NO:2), fused to a sequence, said DNA sequence being operably linked to an eye-specific promoter GMR

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sequence, ~~and expressing said DNA sequence~~, wherein expression of said DNA sequence results in said fly displaying a "rough eye" phenotype.

30 (renumbered as 3). (Currently Amended) A method to identify compounds useful for the treatment, or amelioration of conditions associated with abnormal regulation of the APP pathway comprising assaying for compounds that can modify the "rough eye" phenotypes induced by expression of Abeta<sub>42</sub>, said method comprising:

(a) providing a transgenic fly whose genome comprises a DNA sequence encoding a polypeptide comprising [the] an Abeta portion of human APP wherein said DNA sequence encodes Abeta<sub>42</sub> (SEQ ID NO: 2), fused to a sequence, said DNA sequence being operably linked to an eye-specific promoter GMR sequence, wherein expression of said DNA sequence results in said fly displaying a "rough eye" phenotype;

(b) ~~expressing said DNA sequence, wherein said expression of said DNA sequence results in said fly displaying an altered phenotype referred to as the "rough eye" phenotype~~

(c) administering to said fly a candidate compound; and

(c) assaying for changes in the phenotype of said fly of step (a) as compared to the phenotype of a fly of step (a) not administered the candidate compound.

113 (renumbered as 2). (New) The transgenic fly of claim 3 wherein the eye-specific promoter sequence is the Glass Multimer Reporter (GMR) promoter.

114 (renumbered as 5). (New) The method of claim 30 wherein the eye-specific promoter sequence is the GMR promoter.

In the title:

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The title has been amended to read “Transgenic *Drosophila melanogaster* expressing Abeta42 in the eye”

### **REASONS FOR ALLOWANCE**

The following is an examiner's statement of reasons for allowance:

Claims have been sufficiently narrowed in scope to overcome all grounds of rejection under 35 U.S.C 112, 1<sup>st</sup> paragraph. Claims are now limited to use of an eye-specific promoter and the fly is limited to that which exhibits a rough eye phenotype. Additionally, the method claims have been limited the condition to be treated by identified compounds to those conditions associated with the APP pathway.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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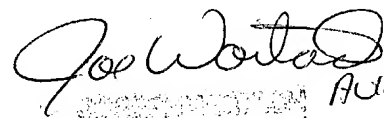
***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio  
Examiner  
Art Unit 1632

  
JOE WINTERS  
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